PATENT USSN 10/044,692 Docket 002640US; 018/213c

#### REMARKS

Claims 1-20 were previously pending in this application, and subject to a Restriction Requirement mailed July 28, 2004.

By way of this paper, certain claims are amended, claims 2-9 are cancelled, and claims 21-38 are newly added. Election of claims for examination on the merits is indicated below.

## Interview Summary

The undersigned thanks Examiner Susan Ungar for the courteous and constructive interview held at the Patent Office on September 2, 2004.

Claim amendments and remarks discussed during the interview are included in this Response.

#### **Amendments**

The amendments to the specification and the claims do not introduce new matter into the disclosure.

Support for the claim amendments and the new claims may be found at various places in the specification. Protein fragments of having up to 100% identity with 20, 50, 100, 200, or more consecutive amino acids of TRT are described *inter alia* in paragraphs [0476] and [0477] of the application as published (US-2003-0096344-A1). Use of TRT fragments, and chimeric proteins made from TRT fragments, to elicit an immune response in mammalian subjects is described in paragraph [0204]. Nucleic acid expression systems such as plasmid and viral vectors, and suitable promoters for inclusion therein are described in paragraphs [0181] to [0183].

The claim amendments are made to obtain coverage for certain aspects of the invention that are of current commercial interest. Applicant reserves the right to introduce claims to subject matter previously claimed or described in the disclosure in this or any other application at a later time.

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## Election of Group for Examination

A restriction has been required between six inventions, which applicants interpret as follows:

- Group 1: Claims 1-3, 6-10, and 20, drawn to a [protein] composition comprising SEQ.
   ID NO:2 or variants thereof; and
- Group 2: Claims 1, 4-5, and 20, drawn to a composition comprising a *polynucleotide* encoding SEQ. ID NO:2 or variants thereof.
- Group 3: Claims 11-12, 14-15, 16 and 18-19, drawn to a method for eliciting an antibody response to hTRT using a *protein* composition;
- Group 4: Claims 11-12, 14-15, 17, and 18-19, drawn to a method for eliciting a cytotoxic T cell response to hTRT using a protein composition;.
- Group 5: Claims 11, 14-15, 16 and 18, drawn to a method for eliciting an antibody response to hTRT [using a polynucleotide]; and
- Group 6: Claims 11, 14-15, 17, and 18, drawn to a method for eliciting a cytotoxic T cell response to hTRT [using a polynucleotide].

Applicants hereby elect Group 2 for examination on the merits, without traverse. Claims 4-5 have been cancelled. New claims 21-33 fall within Group 2; new claims 34-38 fall within Group 1.

Accordingly, the following claims are under examination: Claims 1, 10, 21-33. The other pending claims are withdrawn, subject to the Request for Rejoinder indicated below.

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#### Request for Rejoinder

Groups 5 and 6 are method claims that depend from and incorporate the limitations of product claims in Group 2. Groups 3 and 4 are method claims that depend from and incorporate the limitations of product claims in Group 1. Applicants hereby request that Groups 5 and 6 (and all other method claims depending from product claims in the elected group) be rejoined into the group under examination, in accordance with MPEP § 821.04.

Between Groups 5 and 6, applicants elect Group 5 to be rejoined first, without traverse. Claim 19 has been amended to include subject matter relevant to Groups 5 and 6. This places claims 1, 10-13, 16, 21-33 under examination.

Applicants request that Group 6 subsequently be rejoined with Group 5 upon determination that Group 5 is free of prior art. Claim 11 links the two species together. This would bring claim 17 back into the group under examination.

Applicants further request the Examiner reconsider the restriction between Groups 1 and 2.

MPEP § 803 indicates that a restriction requirement should only be imposed when examination of all the claims would impose a serious burden — whether or not the inventions are patentably distinct.

In the present instance, there is no serious burden incumbent in examining the groups together. For purposes of patentability under 35 USC §§ 102 and 103, the inventions can be determined to be free of prior art by searching the same amino acid sequence: SEQ. ID NO:2. In fact, this search has already been performed in related applications, including parent application USSN 08/912,951 (now U.S. Patent No. 6,475,789). SEQ. ID NO:2 was not previously disclosed to the public before the filing of the priority applications in this series. For purposes of patentability under 35 USC §§ 101 and § 112, the effective use of both proteins and nucleic acids in immunogenic compositions is well established in the art.

Since there would be no serious burden imposed, applicants request that Group 1 be rejoined into the claims under examination. This would save applicants the expense of filing a divisional application, and provide protection for both aspects of the invention, to help promote commercial development.

This would bring all pending claims back into the group under examination.

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# Request for further Interview

Applicant respectfully requests that the application proceed to examination on the merits, in view of the amendment and remarks made herein.

In the event the Examiner determines that a further interview would facilitate prosecution of this application, she is invited to contact applicants' representative at the telephone number indicated below.

#### Fees due

Accompanying this Response are papers authorizing the Commissioner to charge the Deposit account with the fee for an additional 10 claims, and for the one month extension of time.

Should the Patent Office determine that an extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

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